Paper No. 27

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte CHRISTIAN KLEIN,
HANS-PETER JOSEL,
ADA GOERLACH-GRAW,
REINHOLD HILPERT,
FLORIAN BINDER,
JOSEF RITTER, and
RUDOLF ZIMMERMANN

Appeal No. 2001-1587
Application No. 08/506,268

ON BRIEF

Before SCHEINER, ADAMS, and GRIMES, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 2-26. Claim 26 is representative and reads as follows:

26. A method for detecting contamination of a surface by an analyte, comprising:

wiping the surface to be tested with a wiping surface;

providing a capillary active, chromatographic test strip having a planar surface and two ends, with an eluant application zone proximate one end and a target zone proximate the other end, and being in fluid communication therebetween; thereafter

contacting the planar surface of the test strip in an area between the eluant application zone and the target zone with the wiping surface forming a site of contact;

applying eluant onto the eluant application zone to cause the eluant to move toward the target zone and past the site of contact while maintaining contact of the planar surface in said area by the wiping surface in order to take up analyte in the eluant and to move the analyte to the target zone; and thereafter

measuring in the target zone an immunological binding reaction to detect the analyte.

The examiner relies on the following references:

Baier et al. (Baier)	5,118,609	Jun. 2, 1992
Giegel	5,250,412	Oct. 5, 1993
Fitzpatrick et al. (Fitzpatrick)	5,451,504	Sep. 19, 1995

Claims 2-26 stand rejected under 35 U.S.C. § 103 as obvious in view of Fitzpatrick, Giegel, and Baier.

We reverse.

Background

The specification discloses a method for testing a surface for the presence of an analyte such as an illegal drug. See, e.g., page 2. In the disclosed method, the surface to be tested is swabbed with a “wiping surface” that picks up any drug residue that may be present. The wiping surface is then contacted with

a test strip, and contact between the two is maintained while one end of the test strip is contacted with an eluant liquid. The eluant moves up the test strip and elutes the analyte (e.g., drug molecules) from the wiping surface. After the eluant (and any eluted analyte) reaches a "detection zone" at the other end of the test strip, the presence of analyte is determined immunologically. The claims on appeal are directed to this assay method and a test kit for performing the method.

The specification makes clear that a critical feature of the disclosed assay is that contact is maintained during the test procedure between the wiping surface and the test strip. See pages 7-8:

> After wiping a contaminated surface with a wiping surface, an area of the test strip surface contacts said wiping surface between the eluant application zone and the target zone, with a slight pressure being preferably applied. . . .
>
> The pressure exerted on the wiping surface should be sufficient enough to allow a planar fluid contact between the two surfaces.
>
> . . . .
>
> Possible eluting liquids are water or buffer solutions that are conventionally used in immunoassays. The liquid travels along the strip in direction toward the target zone . . . while passing the zone with a pressed-on wiping surface. Surprisingly, it has been found that the analyte molecules adhering to the wiping surface are taken up in the liquid flow and transported to the following zones.

See also the paragraph bridging pages 8 and 9:

> Surprisingly, it has been found that the sensitivity of the method of the invention is significantly higher than that of the prior art. The efficiency of the wiping and transfer of analyte from the wiping surface onto the test strip is against all expectations so high that this method allows the detection of absolute amounts of down to 10 ng of analyte, especially drugs on surfaces. The method involves

> less handling steps and the result can be determined in a very rapid and simple manner.

Appellants' Brief emphasizes that the claims include the limitation of maintaining contact between the wiping surface and test strip during the assay procedure. See pages 3-4: "The key point is that the wiping surface must remain in contact with the contact site while the liquid eluant passes through the contact site . . . in order to increase the amount of analyte carried downstream for immunoassay, so that the method of the present invention is simple and yet more sensitive than prior art methods" (emphasis in original).

Discussion

The examiner rejected all of the claims as obvious over Fitzpatrick, Giegel, and Baier. The examiner characterized Fitzpatrick as "teach[ing] a device . . . and an assay . . . for detecting the presence of an analyte in a sample. The device contains a capillary active, chromatographic test strip having a planar surface and two ends, with an eluant application zone proximate one end and a target zone (detection zone) proximate the other end, with a capture zone (trap zone) in between." Examiner's Answer, page 4. According to the examiner, Fitzpatrick differs from the present claims only in that it "does not teach a wiping surface for collection of analyte nor conducting the contact of the test strip surface with the wiping surface with the aid of a contact pressure device." Id. He relies on Giegel and Baier to make up these differences, citing Giegel as "teach[ing] a swab device for collecting a sample from a surface," and Baier as "teach[ing] a carrier fleece containing cellulose and/or polyester." Id.

The examiner concluded that

> [i]t would have been obvious at the time the invention was made to a person having ordinary skill in the art to use a swab taught by Geigel [sic], utilizing fleece taught by Baier et al[.], to collect a sample from a surface, then to apply the sample to the application zone of the device taught by Fitzpatrick et al[.] either by swapping [sic] the application zone with the fleece swab device, or holding the swab device in contact with the application zone. Eluate would then be applied to the application zone to initiate capillary action to move the analyte through the assay device. By combining these aspects of each of the prior art [references], one would have a commercially viable device and technique in a convenient kit which could be used under a variety of field conditions for the detection of harmful and/or illegal substances.

Id., pages 4-5.

"In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a prima facie case of obviousness. Only if that burden is met, does the burden of coming forward with evidence or argument shift to the applicant." In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). "Measuring a claimed invention against the standard established by section 103 requires the oft-difficult but critical step of casting the mind back to the time of invention, to consider the thinking of one of ordinary skill in the art, guided only by the prior art references and the then-accepted wisdom in the field." In re Dembiczak, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999).

In this case, the references relied on by the examiner do not support a prima facie case of obviousness. The examiner's characterization of Fitzpatrick overstates its relevance. In the claimed assay, a wiping surface is applied to, and maintained in contact with, a test strip and analyte is eluted from the sample

by an eluant liquid. In Fitzpatrick's assay, the sample is applied in a liquid to one end of the test strip, and interacts with various other components as it is drawn through the strip by capillary action. See column 1, lines 46-65:

> The assay method of the present invention provides for moving a sample suspected of containing an analyte through three zones. . . .
>
> [S]ample is applied to the first zone, and movement of sample through the first zone mobilizes receptor. If analyte is present in the sample, analyte and receptor will bind to form a stable receptor-analyte complex. The receptor-analyte complex moves through the second trap zone, substantially unaffected by the immobilized ligand, and into the third zone, where it is detected.

Fitzpatrick differs from the instant claims in that it does not teach, at least, the limitation of "maintaining contact of the planar surface [of the test strip] by the wiping surface." With respect to this limitation, the examiner argues that "[m]aintaining contact between the swab and the test strip would fall with[in] routine maximization of analyte sample transfer techniques." Examiner's Answer, page 7. However, he cites no evidence to support this assertion.

The examiner's position appears to be based on hindsight. The examiner has cited no evidence to show that maintaining contact between a swab and a test strip was a routine method of transferring sample. The examiner's unsupported assertion is not enough to show that this limitation would have been obvious to those of skill in the art. See In re Lee, 277 F.3d 1338, 61 USPQ2d 1430 (Fed. Cir. 2002). See also W.L. Gore & Assocs., Inc. v. Garlock, Inc., 721 F.2d 1540, 1552, 220 USPQ 303, 312-313 (Fed. Cir. 1983): "To imbue one of ordinary skill in the art with knowledge of the invention . . . , when no prior art reference or references of record convey or suggest that knowledge, is to fall

victim to the insidious effect of a hindsight syndrome wherein that which only the inventor taught is used against its teacher." .

Summary

The references cited by the examiner do not support a prima facie case of obviousness. We therefore reverse the rejection under 35 U.S.C. § 103.

REVERSED

Toni R. Scheiner	)
Administrative Patent Judge	)
	)
	)
	) BOARD OF PATENT
Donald E. Adams	)
Administrative Patent Judge	) APPEALS AND
	)
	) INTERFERENCES
	)
Eric Grimes	)
Administrative Patent Judge	)

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